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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,637	10/03/2000	Daniel A. Japuntich	48317USA5L.031	7360

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EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/677,637	JAPUNTICH ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/21/2006 (RCE)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-36,38-62 and 64-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *71-78* is/are allowed.

6)☒ Claim(s) *33-36,38-62,64-69 and 79-93* is/are rejected.

7)☒ Claim(s) *70* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 02/21/2006 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 33-36,38-62,64-69,79-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. ('516) in view of Soderberg (EP 0 252 890 A1), Braun ('362) and Warbasse ('706).

As to claim 33, Simpson et al. (figs.1 and 2) disclose a filtering face mask that comprises: (a) a mask body that is adapted to fit over the nose and mouth of a wear; (b) an exhalation valve (13) that is attached to the mask body, the exhalation valve comprising: (1) a valve seat that comprises: (i) a seal surface; and (ii) an orifice (16) that is circumscribed by the seal surface; (2) a single flexible flap (15) that has a fixed

portion (17) and a free portion and first and second opposing ends, the first end of the single flexible flap being associated with the fixed portion of the flap so as to remain at rest during an exhalation, and the second end being associated with the free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the second end also being located below the first end when the filtering face mask is worn on a person, the flexible flap being positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith, under any orientation of the valve, when no external forces from the movement of fluid are exerted upon the flap. To the extent, if any, that the flap of Simpson et al. may not be pressed towards the seal surface in an abutting relationship therewith, under any orientation of the valve, when no external forces from the movement of fluid are exerted upon the flap, resort is had to Soderberg (page 4, lines 17-23), in a face mask having an exhalation valve that is pressed towards the valve seal surface in an abutting relationship therewith, under any orientation of the valve when no external forces from the movement of fluid are exerted upon the flap for the purpose of ensuring and maintaining a seal between the exhalation valve and the valve seat.

It would have been obvious to modify the exhalation valve of Simpson et al. to be pressed towards the valve seat in an abutting relationship therewith because it would have ensured and maintained a seal between the valve flap and seat as taught by Horda.

The differences between Simpson et al. and claim 1 are a valve cover that is disposed over the valve seat and that comprises: (i) an opening the is disposed directly

in the path of fluid flow when the free portion of the flexible flap is lifted from the seal surface during an exhalation; (ii) a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first end to the second end; and (iii) cross members that are disposed within the opening of the valve cover.

Warbasse teaches a valve cover (11) having a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first end to the second end for the purposes of protecting the valve flap (12), controlling the extent of movement of the valve flap, controlling the direction of fluid flow exiting the mask via the valve.

It would have been obvious to modify the valve (fig.2) of Simpson et al. to provide a valve cover because it would have provided a means for protecting the valve flap (12), controlling the extent of movement of the valve flap, controlling the direction of fluid flow exiting the mask via the valve as taught by Warbasse.

Braun, in an exhalation valve for a filtering face mask, teaches cross members (25) that are disposed within the opening of the valve cover for the purpose of protecting the valve against debris (col.4, lines 25-26).

It would have been obvious to modify the opening of the valve cover of Simpson et al. as modified by Warbasse to include cross members therein because it would have protected the valve against debris as taught by Braun.

As to claim 34, Warbasse teaches a valve cover (11 of fig.2) having an opening in the valve cover which is approximately parallel to the path traced by the second end of the flexible flap during its opening and closing.

As to claim 35, Simpson et al. as modified by Warbasse teaches a cover (11 of fig.2)and its opening direct exhaled air downwards when the mask is worn by a person.

As to claim 36, the cover of Warbasse (11 of fig.2) illustrates fluid impermeable sidewalls (made of aluminum as disclosed at page 1, lines 70-77).

As to claim 38, the opening in the cover of Simpson et al. as modified by Warbasse (fig.2) is at least the size of the orifice (e.g. 16 of Simpson et al.) in the valve seat.

As to claims 39,40, the valves (fig.2) of Simpson et al. (page 2, lines 37-65) are disclosed as being made of plastic and/or rubber material. It would have been obvious to fabricate the valves by any well known technique including the technique of injection molding. Further, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Inasmuch as injection molding is a widely employed technique in the fabrication of plastic and rubber materials, it would have been obvious to make the valve of Simpson et al. from a variety of well known techniques including injection molding.

As to claim 41, Simpson et al. disclose the flexible flap being pressed towards the seal surface such that there is a substantially uniform seal when the valve is in a closed position (page 2, lines 39-42). The seal (figs.2 and 3) of Simpson et al. is illustrated as being substantially uniform and since the flexible flap (15) of Simpson et al. is disclosed

of being made from plastic and since known physical characteristics of plastics include flexibility and resiliency, it would have been obvious that the flap (15) of Simpson et al. being made from plastic is "...capable of allowing the flap to display a bias towards the seal surface.".

As to claim 43, the flexible flap (15) of Simpson et al. is disclosed as being made of flexible plastic and as such is fully capable of performing the recited function of resisting permanent set and creep.

As to claims 44 and 47, the flexible flaps (15,18) of Simpson et al. are disclosed as being made of plastic and/or rubber for example (page 2, line 39 and line 53). It would have been obvious to make the flexible flap from any well known flexible material including and elastomeric rubber such as a polyisoprene as mere substitution of one well known flexible material for another and because elastomeric rubber is a well known material from which to make valve flaps.

As to claims 45 and 46, the degree of a seal between the valve flap and valve sealing surface of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular degree of seal including one meeting the standards as set forth in 30 C.F.R. 11.183-2, July 01, 1991. Further, it stands to reason that one of ordinary skill in the art would strive to make the face mask in accordance with at least minimum current government standards of operation including one having a valve flap having a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hrs. at 70 degrees centigrade.

As to claims 48-51,53,54, the particular dimensions, the particular material including the hardness of the material of the flexible flap (15,14) of Simpson et al. can be arrived at through mere obvious experimentation and observation with no criticality seen in any particular dimensions nor in any particular constituency. One of ordinary skill would recognize that the particular dimensions and the particular material including hardness of the material would have been dependent upon the airflow requirements of a group of wearers, that is, an adult would require a mask and valve of a size and material that is capable of handling respiratory airflows typical of adults whereas a child or an adult with a compromised respiratory system would require a mask and valve of a size and material that is capable of handling lesser respiratory airflows.

As to claim 55, while Simpson et al. is silent as to the relative surface areas of the fixed and free portions of flap (15), it is submitted that the particular relative amounts of the fixed and free portions can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular relative amounts. The relative amounts of surface areas are dependent upon the particular shape and size of the valve flaps being employed and dependent upon the particular respiratory requirements of the intended wearer (i.e. adults require valves capable of handling larger airflows and differential pressures thus requiring valves having different sealing characteristics).

As to claim 56, the flange against which the valve flap is secured in Simpson et al. (fig.2) is illustrated as being the same 360 degrees around the valve seat.

As to claim 57, given the downward orientation of the mask body (1,2) of Simpson et al. fig.1 and given that any exhaled air must pass outward between the valve flap (15,14) and the body of the mask, it stands to reason that exhaled air will follow a path which generally parallel to the upper surface of the body of the mask which itself is downwardly oriented as illustrated in fig.1. Therefore, exhaled air is deflected downwardly during use of the mask of Simpson et al..

As to claim 58, Simpson et al. (fig.2) illustrate a plurality of openings within the orifice (16) having cross members there between; otherwise, Simpson et al. as modified by Braun teach a plurality of openings between cross members (18,19 of Braun) within the orifice.

As to claims 59-61, while Simpson et al. do not address the particular volume of a wearer's exhalation exiting the exhalation valve (12), it is submitted that since the exhalation valve (12) is expressly disclosed as opening in response to a wearer's exhalation, it would have been obvious that the valve would remain opened as long as a wearer is exhaling which would enable most if not all of the volume including 60-70% of gas exhaled by a wearer to pass through valve (12) of Simpson et al..

As to claim 62, since the mask body (1,2) of Simpson et al. is angled downwardly when positioned on a wearer's face, the valve (12) on mask body (1,2) of Simpson et al. is positioned substantially opposite a wearer's mouth (fig.1). The valve flap (15) of Simpson et al. is mounted on the valve seat (fig.2) in cantilever fashion.

As to claim 64, the shape of the orifice (16) of Simpson et al. does not wholly correspond to the shape of the seal surface inasmuch as the seal surface forms a perimeter around the orifice.

As to claim 65, Simpson et al. as modified by Soderberg, Braun and Warbasse as discussed above with respect to claim 33, also teach a fluid impermeable ceiling that is spaced further from the valve seat above the free segment of the flap's peripheral edge than above the stationary segment of the flap's peripheral edge (see #11 of fig.2 of Warbasse).

As to claim 66, Simpson et al. as modified by Soderberg, Braun and Warbasse as discussed above with respect to claim 33, also teach a fluid impermeable ceiling that is higher above the free segment of the flap's peripheral edge than above the stationary segment of the flap's peripheral edge (see #11 of fig.2 of Warbasse).

Claims 67 and 69 are substantially equivalent in scope to claim 33 and are included in Simpson et al. as modified by Soderberg, Braun and Warbasse for the reasons set forth above with respect to claim 33.

As to claim 68, Simpson et al. (fig.2) illustrate the single flexible flap (15) has only one free portion.

As to claims 79,85 and 91, Simpson et al. as modified by Soderberg, Braun and Warbasse as discussed above with respect to claim 33 also teach a mask body that is adapted to fit over the nose and mouth of a wearer and that comprises a filtration layer (see Simpson et al. page 1, lines 108-113).

As to claims 80,86, Simpson et al. as modified by Braun and Warbasse teach the valve cover opening (#11 of Warbasse) comprises cross members (#25 and col.4, lines 25-26 of Braun), and wherein the exhalation valve is attached to the mask body directly in front of a wearer's mouth would be when the mask is worn (fig.1 of Simpson et al.), and wherein essentially an entire exposed surface of the mask body is fluid permeable to air during inhalation (Simpson et al. page 1, lines 108-113).

As to claims 81,87, Simpson et al. (fig.2) illustrate the flap (15) being mounted to the valve seat in cantilevered fashion.

As to claims 82,83,88,89, the opening in the cover (11 of Warbasse) is at larger than the orifice (16 of Simpson et al.) in the valve seat.

As to claims 84,90, Simpson et al. (fig.1) as modified by Warbasse (fig.2) teach the valve cover opening being disposed directly in the path of exhaled airflow.

As to claim 92, Simpson et al. (fig.2) illustrate a plurality of openings within the orifice (16) having cross members there between; otherwise, Simpson et al. as modified by Braun teach a plurality of openings between cross members (18,19 of Braun) within the orifice.

As to claim 93, given the downward orientation of the mask body (1,2) of Simpson et al. fig.1 as modified by Warbasse (#11 of fig.2) and given that any exhaled air must pass outward between the valve flap (15,14) and the body of the mask, it stands to reason that exhaled air will follow a path which generally parallel to the upper surface of the body of the mask which itself is downwardly oriented as illustrated in fig.1 of

Simpson et al.. Therefore, exhaled air is deflected downwardly during use of the mask of Simpson et al..

Allowable Subject Matter

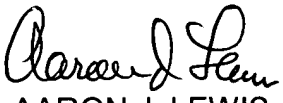
4. Claim 70 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Claims 71-78 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



AARON J. LEWIS

Primary Examiner
Art Unit 3743

Aaron J. Lewis
March 07, 2006